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(v) Information allowing clinicians to gauge clinical risk associated with integrating the EEG interpretive assessment aid into their diagnostic pathway.

(vi) Information allowing clinicians to understand how to integrate the device output into their diagnostic pathway when the device is unable to provide a classification or final result.

[80 FR 16268, Mar. 27, 2015]

§ 882.1460 Nystagmograph.

(a) *Identification.* A nystagmograph is a device used to measure, record, or visually display the involuntary movements (nystagmus) of the eyeball.

(b) *Classification.* Class II (performance standards).

§ 882.1470 Computerized cognitive assessment aid.

(a) *Identification.* The computerized cognitive assessment aid is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an interpretation of the current level of cognitive function. The computerized cognitive assessment aid is used only as an assessment aid to determine level of cognitive functioning for which there exists other valid methods of cognitive assessment and does not identify the presence or absence of clinical diagnoses. The computerized cognitive assessment aid is not intended as a stand-alone or adjunctive diagnostic device.

(b) *Classification.* Class II (special controls). Except when the computerized cognitive assessment aid is intended for diagnostic assessment of specific diseases or conditions and relies on inputs from visual cues, auditory cues, and/or functional use of the hand, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The special control(s) for this device are:

(1) The technical parameters of the device's hardware and software must be fully characterized and be accompanied by appropriate non-clinical testing:

(i) Hardware specifications must be provided. Appropriate verification, validation, and hazard analysis must be performed.

(ii) Software, including any proprietary algorithm(s) used by the device to arrive at its interpretation of the patient's cognitive function, must be described in detail in the software requirements specification (SRS) and software design specification (SDS). Appropriate software verification, validation, and hazard analysis must be performed.

(2) The device must be designed and tested for electrical safety.

(3) The labeling must include:

(i) A summary of any testing conducted to demonstrate how the device functions as an interpretation of the current level of cognitive function. The summary of testing must include the following, if available: Any expected or observed adverse events and complications; any performance measurements including sensitivity, specificity, positive predictive value (PPV), and negative predictive value (NPV) per the devices intended use; a description of the repeatability of measurements; a description of how the cut-off values for categorization of measurements were determined; and a description of the construct validity of the device.

(ii) A warning that the device does not identify the presence or absence of clinical diagnoses.

(iii) A warning that the device is not a stand-alone diagnostic.

(iv) The intended use population and the intended use environment.

(v) Any instructions technicians must convey to patients regarding the administration of the test and collection of cognitive test data.

[80 FR 49138, Aug. 17, 2015, as amended at 84 FR 71815, Dec. 30, 2019]

§ 882.1471 Computerized cognitive assessment aid for concussion.

(a) *Identification.* The computerized cognitive assessment aid for concussion is a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an indication of the current level of cognitive function in response to concussion. The computerized cognitive assessment aid for concussion is used only as an assessment aid in the management of concussion to determine cognitive function for patients after a potential